

***Amendments to the Claims:***

This listing of claims will replace all prior versions, and listings, of claims in the application:

***Listing of Claims:***

Claims 1-27. (canceled)

Claim 28. (Currently amended) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of Factor VIIa for treating trauma bleeding in hemophilia patients, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-like peptide 1 (GLP-1), and Copaxone; and ~~non-covalently bound to one or more colloidal particles, the~~

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, wherein the protein or polypeptide ~~is selected from the group consisting of:~~ is non-covalently bound to the one or more colloidal particles and

~~(a) Factor VIIa, granulocyte colony stimulating factor (G-CSF), granulocyte macrophage colony stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-like peptide 1 (GLP-1) and Copaxone; or~~

~~(b) proteins or polypeptides that comprise a consensus sequence of S/T-X-  
L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V,  
E and Q have their standard meanings;~~

~~wherein the protein or polypeptide is not Factor VIII (FVIII), and the protein or  
polypeptide is not encapsulated in the one or more colloidal particles.~~

Claim 29. (Currently amended) The pharmaceutical composition of claim 28<sub>1</sub> wherein the  
colloidal particles are substantially neutral and the polymer carries substantially no net  
charge.

Claim 30. (Currently amended) The pharmaceutical composition of claim 28<sub>1</sub> wherein the  
colloidal particles have a mean particle diameter of between about 0.03 to about 0.4  
microns.

Claim 31. (Currently amended) The pharmaceutical composition of claim 30<sub>1</sub> wherein the  
colloidal particles have a mean particle diameter of approximately 0.1 microns.

Claim 32. (Currently amended) The pharmaceutical composition of claim 28<sub>1</sub> wherein the  
amphipathic lipid is a phospholipid from natural or synthetic sources.

Claim 33. (Currently amended) The pharmaceutical composition of claim 32<sub>1</sub> wherein the  
amphipathic lipid is phosphatidylethanolamine (PE).

Claim 34. (Currently amended) The pharmaceutical composition of claim 28<sub>1</sub> wherein the amphipathic lipid is a carbamate-linked uncharged lipopolymer.

Claim 35. (Currently amended) The pharmaceutical composition of claim 28<sub>1</sub> wherein the amphipathic lipid is aminopropanediol distearoyl (DS).

Claim 36. (Currently amended) The pharmaceutical composition of claim 28, wherein the colloidal particles further comprise a second amphipathic lipid obtained from either natural or synthetic sources.

Claim 37. (Currently amended) The pharmaceutical composition of claim 36<sub>1</sub> wherein the second amphipathic lipid is phosphatidylcholine.

Claim 38. (Currently Amended) The pharmaceutical composition of claim 36<sub>1</sub> wherein ~~cholesterol is supplemented to the composition~~ further comprising cholesterol.

Claim 39. (Currently amended) The pharmaceutical composition of claim 28<sub>1</sub> wherein the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 40. (Currently amended) The pharmaceutical composition of claim 39<sub>1</sub> wherein the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 41. (Currently amended) The pharmaceutical composition of claim 40, wherein the polyethylene glycol has a molecular weight of between about 500 to about 5000 daltons.

Claim 42. (Currently amended) The pharmaceutical composition of claim 41, wherein the polyethylene glycol has a molecular weight of approximately 2000 daltons.

Claims 43-44. (Canceled)

Claim 45. (Withdrawn and Currently Amended) The pharmaceutical composition of claim 28, wherein the polypeptide is Factor VIIa, and the composition may be used in hemophilia patients with inhibitors and for the treatment of trauma bleeding in hemophilia patients.

Claim 46. (Canceled)

Claim 47. (Currently Amended) A method for treating a patient suffering from a disease that is known to be treatable multiple sclerosis with a protein or polypeptide known to effectively treat the disease, comprising administering to ~~[[a]]~~ the patient in need thereof a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of Copaxone ~~the protein or polypeptide~~ non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, wherein the protein or polypeptide is selected from the group consisting of:

(a) ~~Factor VIIa, granulocyte colony stimulating factor (G-CSF), granulocyte macrophage colony stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-like peptide 1 (GLP-1) and Copaxone; or~~

(b) ~~proteins or polypeptides that comprise a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;~~

~~wherein the protein or polypeptide is not Factor VIII (FVIII), and the protein or polypeptide~~ Copaxone ~~is not encapsulated in the one or more colloidal particles.~~

Claims 48-49. (Canceled)

Claim 50. (Currently amended) A method for treating a patient suffering from a disease that is known to be treatable with a protein or polypeptide Copaxone ~~known to effectively treat the disease~~, comprising administering to a patient in need thereof a therapeutically effective amount of the ~~protein or polypeptide selected from the group consisting of:~~

(a) ~~Factor VIIa, granulocyte colony stimulating factor (G-CSF), granulocyte macrophage colony stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-like peptide 1 (GLP-1) and Copaxone; or~~

(b) ~~proteins or polypeptides that comprise a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings; and~~

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the one or more colloidal particles and Copaxone ~~the protein or polypeptide~~ are administered separately.

Claims 51-52. (Canceled)

Claim 53. (Currently amended) The method of claim 50, wherein the ~~protein or polypeptide is Copaxone~~ amphipathic lipid is selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer and aminopropanediol distearoyl (DS).

Claim 54. (Currently amended) A method for treating a patient suffering from hemophilia ~~a disease that is known to be treatable with a protein or polypeptide known to effectively treat the disease, comprising:~~

administering to a patient in need thereof a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the ~~protein or polypeptide~~ Factor VIIa non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

~~wherein the protein or polypeptide is selected from the group consisting of Factor VIIa, granulocyte colony stimulating factor (G-CSF), granulocyte macrophage colony stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon like peptide 1 (GLP-1) and Copaxone,~~  
and

wherein Factor VIIa ~~the protein or polypeptide~~ is not encapsulated in the colloidal particles.

Claims 55-56. (Canceled)

Claim 57. (Currently amended) A method for extending the half-life of a protein or polypeptide in vivo, comprising:

providing a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, the protein or polypeptide is selected from the group consisting of ~~Factor VIIa~~, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-*like* peptide 1 (GLP-1) and Copaxone; and

administering the pharmaceutical composition to a patient,

wherein the protein or polypeptide is not encapsulated in the colloidal particles.

Claim 58. (New) A pharmaceutical composition for treating trauma bleeding in hemophilia patients via parenteral administration, comprising:

a therapeutically effective amount of Factor VIIa; and

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein Factor VIIa is non-covalently bound to the one or more colloidal particles and Factor VIIa is not encapsulated in the one or more colloidal particles.

Claim 59. (New) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-like peptide 1 (GLP-1) and Copaxone; and

one or more colloidal particles having a mean particle diameter of from 0.03 to 0.4 microns, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is non-covalently bound to the one or more colloidal particles.

Claim 60. (New) The pharmaceutical composition of claim 59, wherein the amphipathic lipid is selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer and aminopropanediol distearoyl (DS).

Claim 61. (New) The pharmaceutical composition of claim 60, wherein the amphipathic lipid is aminopropanediol distearoyl (DS).



Claim 62. (New) The pharmaceutical composition of claim 60, wherein the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 63. (New) The pharmaceutical composition of claim 61, wherein the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 64. (New) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-*like* peptide 1 (GLP-1) and Copaxone; and

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is non-covalently bound to the one or more colloidal particles.

Claim 65. (New) The pharmaceutical composition of claim 63, wherein the amphipathic lipid is selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer, and aminopropanediol distearoyl (DS).

Claim 66. (New) The pharmaceutical composition of claim 65, wherein the amphipathic lipid is aminopropanediol distearoyl (DS).

Claim 67. (New) The pharmaceutical composition of claim 65, wherein the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 68. (New) The pharmaceutical composition of claim 67, wherein the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 69. (New) The pharmaceutical composition of claim 58, wherein the amphipathic lipid is selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer, and aminopropanediol distearoyl (DS).

Claim 70. (New) The pharmaceutical composition of claim 69, wherein the amphipathic lipid is aminopropanediol distearoyl (DS).

Claim 71. (New) The pharmaceutical composition of claim 58, wherein the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 72. (New) The pharmaceutical composition of claim 71, wherein the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 73. (New) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-*like* peptide 1 (GLP-1) and Copaxone;

one or more colloidal particles comprising

approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

a second amphipathic lipid obtained from either natural or synthetic sources; and

cholesterol,

wherein the protein or polypeptide is non-covalently bound to the one or more colloidal particles and is not encapsulated in the one or more colloidal particles.

Claim 74. (New) A pharmaceutical composition for parenteral administration, comprising:

a therapeutically effective amount of a protein or polypeptide selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon  $\gamma$ , glucagon-*like* peptide 1 (GLP-1) and Copaxone; and

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid selected from the group consisting of phosphatidylethanolamine (PE), a carbamate-linked uncharged lipopolymer and

aminopropanediol distearoyl (DS), the amphipathic lipid is derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is non-covalently bound to one or more colloidal particles, and the protein or polypeptide is not encapsulated in the one or more colloidal particles.